**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

MDL No. 986 JFG
Case No. 1:93cv7452

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|---|
| IN RE FACTOR VIII OR IX CONCENTRATE BLOOD PRODUCTS PRODUCTS LIABILITY LITIGATION |

**DECLARATION OF PROFESSOR HANNO MERKT**

I, PROFESSOR HANNO MERKT, hereby make this sworn statement pursuant to 28 U.S.C. § 1746. I have been asked by Counsel for the Plaintiffs in the above captioned case to provide my opinion on some aspects of German law relevant to this action, including the availability of the German courts to try the claims brought by German plaintiffs before this Court and some additional aspects relating to litigation of these claims before the German courts. My opinion is based on my work, experience as a lawyer and as a judge, and publications with respect to German law.

## I. STATEMENT OF QUALIFICATIONS

1. I currently hold the chair in Comparative and International Private Law at the Albert-Ludwigs-University Freiburg, Germany. I have held this position since October 2003. In addition, in 2007, I was appointed judge at the Court of Appeals of Karlsruhe.

2. I studied law at the Universities of Bonn, Münster, and Chicago and received my initial law degree from the University of Bonn in 1987, my doctoral degree from the University of Münster and a degree of Master of Laws from the University of Chicago in 1989. I was admitted to the New York Bar in 1990 and, after taking the second state exam, was admitted to the Hamburg Bar in 1993. From 1990 until 2000, I was Research Associate at the Max-Planck-Institute in Hamburg and Lecturer in Law at the University of Hamburg. In 2000, I received my habilitation from the University of Hamburg. From 2000 until 2003, I held the Alfried-Krupp-Chair for Private Law and Business Law at Bucerius Law School, the first private law school in Germany. I have also taught at the University of Regensburg, the University of Ulm, and the University of Vaduz in Liechtenstein, and I have been visiting scholar at the University of Chicago Law School, at Harvard Law School, and at New York University Law School.

3. My main academic interests are in the areas of civil law, commercial and corporate law, securities regulation, conflicts of law and international civil procedure. I have published a number of books, commentaries, and articles on various issues of German, European, International, Comparative Civil, Commercial and Corporate Law. Additional information regarding my current position is available at http://www2.jura.uni-freiburg.de/institute/ipr2/german/ home.php. My curriculum vitae and a list of my publications are attached as Exhibit A to this declaration.

## II. DOCUMENTS REVIEWED

4. In examining the legal issues of German law pertaining to this opinion, I have reviewed the following documents that were furnished to me by Counsel for the Plaintiffs:

(i) Plaintiffs' Complaint for Damages and Injunctive Relief, dated April 19, 2005 ("Plaintiffs' Complaint").

(ii) Decision by the U.S. Court of Appeals for the Seventh Circuit, No. 06-1427, *In Re Factor VIII or IX Concentrate Blood Products Liability Litigation, Domenico Gullone, et al., v. Bayer Corporation, et al.*, dated May 4, 2007 ("Gullone").

(iii) Declaration of Professor Joachim Zekoll, dated September 30, 2007 ("Zekoll Declaration").

(iv) Memorandum in Support of Defendants' Motion to Dismiss Plaintiffs from Germany on Grounds of Forum Non Conveniens, dated October 1, 2007 ("Memorandum").

## III. SUMMARY OF CONCLUSIONS

5. For substantive and procedural reasons outlined below, German courts are not competent to hear the current case. German civil procedure is inadequate to provide plaintiffs with an adequate proceeding. Moreover, German substantive law, both the law of tort and strict rules of 'but for' causation and the law of pharmaceutical products liability law will effectively not permit this litigation to proceed in Germany.

## IV. OPINION

### A. Jurisdiction

6. Under German law, the competent court to hear tort claims is the court where the tortious conduct took place, see Sec. 32 Civil Procedure Act. If the place of conduct and the place where the damage occurs are different, the plaintiff may determine the competent

court by way of election. If the plaintiff opts for the court where the tortious conduct took place, that court has jurisdiction to hear the case. More importantly for these purposes, if, the plaintiff opts for that court, the court where the damage occurs has no jurisdiction to hear the case.[1] Accordingly, since the plaintiffs in the current case have opted for the U.S. courts, German courts are not competent to hear the case.

7. The conclusion of the Zekoll Declaration that Germany is the better forum for the current case is based on Germany's alleged "desire to adjudicate locally allegations of **serious misconduct in Germany** to protect the integrity of German medical care and regulations." (Zekoll Declaration at ¶33, emphasis added). This conclusion is clearly wrong and Professor Zekoll admits as much. The United States is where the relevant acts of the Defendants occurred as opposed to the Germany which Professor Zekoll describes as "the place where the consequences of that action (that is, the damages/injuries of the plaintiff) occurred." (*Id.* at ¶12). Accordingly, there is no such interest of Germany to adjudicate the case.

8. As the Zekoll Declaration correctly points out, the German Government has set up a foundation with funds to compensate hemophiliacs infected with HIV. (*Id.* at ¶ 32). However, the conclusion that because of that compensation program Germany would have a strong interest in having the current case adjudicated before German courts (*id.*) is incorrect. The opposite is correct: German law provides that individuals with hemophilia who elect to participate in the compensation program are barred from pursuing litigation based on the same injuries. Accordingly, the law draws a clear line between those seeking the protection of the domestic program (the object of the specific interest of the Government) and those who opt for

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[1] Jan Kropholler, *Internationales Privatrecht*, 6th ed., p. 620 (2006); Heinrich Nagel & Peter Gottwald, *Internationales Zivilprozessrecht*, 6th ed., p. 181 (2007).

pursuing litigation. If a plaintiff opts out of the program by pursuing litigation, there is no specific interest of the German Government to have the case heard before a German court.

**B. Substantive Law**

9. As opposed to U.S. law in some states, German law does not accept market share liability. Instead, German law adheres strictly to the "but for" standard in causation issues. An extension of liability to those cases in which a defendant is held responsible simply because he or she belongs to a group of tortfeasors would clearly violate German law. According to Sec. 823 Subs. 1 and Sec. 830 Subs. 1 of the German Civil Code a specific and individual relationship between the damage and the tortfeasor has to be established and proven by plaintiff.[2] Accordingly, for the many German clients who are unable to identify which of the Defendants' products infected them, their claims will be barred.

10. The Zekoll Declaration alleges that "German Courts have heard numerous cases brought by persons with hemophilia or others claiming infection through their use of factor concentrates or from blood transfusion." The Declaration goes on to explain that "Section 84 of the Pharmaceuticals Act establishes a liability [...] when a drug causes death or [...] injury." This proposition stands in clear contradiction to what renowned experts of German pharmaceutical products liability have said. For example, Professor Erwin Deutsch, one of the most respected specialists in the field of medical malpractice and pharmaceutical products

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[2] Federal Supreme Court, decision of January 11, 1994 (VI ZR 41/93), *Neue Juristische Wochenschrift,* p. 932 (1994); Gert Brüggemeier, *Prinzipien des Haftungsrechts - Eine systematische Darstellung auf rechtsvergleichender Grundlage,* p. 161 seq. (1999); Uwe Diederichsen, *Ausbau des Individualschutzes gegen Umweltbelastungen als Aufgabe des bürgerlichen und des öffentlichen Rechts*, Expert Opinion for the 56th German Lawyers Conference, Opinion L, p. 48, 89 seq. (1986); for further references see Gerald Spindler, in: Heinz Georg Bamberger & Herbert Roth (eds.), *Kommentar zum Bürgerlichen Gesetzbuch*, § 830 no. 37 (2003); Jürgen Oechsler, in: *Julius von Staudingers Kommentar zum Bürgerlichen Gesetzbuch*, § 4 ProdHaftG no. 50 seq. (2002); Gerhard Wagner, in: *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 4th ed., § 1 ProfHaftG no. 75 (2004).

liability in Germany only recently in his Commentary on the Pharmaceutical Act expressed his deep concern over the poor state of German pharmaceutical products liability practice. "Liability for injuries caused by pharmaceutical products has been regulated in some detail in Germany. Yet, cases of pharmaceutical products liability are rarely brought before German courts. In general, it is surprising that medical malpractice cases are much more frequent than pharmaceutical products liability cases." And he goes on to summarize: "All in all, the statutory regime shows that neither [German] fault liability nor no fault liability are capable of sufficiently covering the necessary pharmaceutical products liability"[3] And in the preface of the Commentary on the Pharmaceutical Act he notes: "The cases with HIV-infected blood products have clearly shown the limitations of the Pharmaceutical Act."[4] (translation by undersigned).

## C. Procedural Matters

### 1. General

11. As Professor Zekoll acknowledges, German civil procedure completely lacks any pre-trial discovery. There is no mechanism under German law that would permit plaintiffs to gather documents and testimony in preparation of the trial on the merits. Moreover, a party who seeks to discover a document from the opposing party must indicate to the court which document is being sought, what the relevance of such document would be, and where it is likely to be found. Hence, while documents from the other party may be obtained by judicial order, this is on a condition that the documents be specifically described, both as to what they contain or may contain and as to the location where the documents can be found. As the Zekoll Declaration put it correctly, the party seeking compelled production of a document has to know the very

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[3] See Erwin Deutsch, in: Erwin Deutsch & Hans-Dieter Lippert (eds.), *Kommentar zum Arzneimittelgesetz (AMG)*, 2nd ed., p. 672 (2007), attached as Exhibit B, hereto.

[4] *Id.* preface.

existence of such document in order to make reference to it. (*Id.* at ¶ 25). Hence, it is not possible under German law to search for unknown documents via pre-trial discovery. This is particularly cumbersome in the current case in which most of the evidence, particularly all evidence with regard to tortious conduct committed by defendants is located within the U.S.

12. As the Zekoll Declaration states, "if these cases were to remain in the United States, discovery of evidence located in Germany would be limited to discovery available under the Hague Convention." (*Id.* at ¶ 30). The Declaration fails, however, to mention that if the cases were to be refiled in Germany, pretrial discovery of the U.S.-type would be completely barred, as set out previously. Moreover, German courts would be willing to, and on a regular basis, provide through Letters Rogatory discovery sought from U.S. litigation that is sufficiently identified.

13. In contrast to the U.S., in Germany a plaintiff runs the risk of having to indemnify his opponent for his legal costs, including attorney's fees, in case he loses the action. Legal aid under German law (Prozesskostenhilfe, Secs. 114 seq. Civil Procedure Act) may mitigate some of these costs but it is only available to litigants of very modest means.

14. Finally, if the cases were refiled in Germany and the plaintiffs would be successful in the end, enforcement of the German judgment in the U.S. would require a separate and additional recognition and enforcement proceeding before U.S. courts in order to get the German judgment recognized and enforced.

**2. <u>Mass Tort Litigation</u>**

15. As opposed to the mechanisms for mass tort litigation in the U.S., in Germany, there is no suitable type of mass proceeding for a case of this size or nature under German law. Each of the mechanisms - joinder (*Streitgenossenschaft*, Secs. 59, 60 Civil Procedure Act); consolidation of actions (*Verfahrensverbindung*, Sec. 147 Civil Procedure Act);

and sample proceeding (*Musterverfahren*) – are not appropriate for this litigation. The latter is available only for administrative proceedings not for civil litigation. Consolidation is only applicable for claims brought in the same court and my understanding is that the plaintiffs here come from all over Germany and, were they able to re-file in Germany, they would do so in numerous courts. Finally, joinder is not viable for similar reasons: claims can be joined so long as they are brought by the same attorney in a single venue.

16. Another factor in comparing German and U.S. procedure law is the competence of lawyers to handle collective proceedings. German lawyers simply are not experienced or familiar enough with complex multi-party proceedings to effectively or willingly engage in this type of litigation. By contrast, the frequency of mass tort litigation in the U.S. over the past twenty or so years has produced an array of specialists in the art of case management and role of lead counsel.

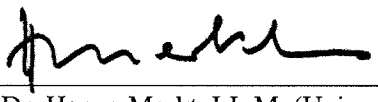
17. The Zekoll Declaration asserts that "German judges are permitted to consider evidence in foreign languages such as English without translation." (at ¶ 29). This assertion is hypothetical at best. In fact, in a complex and fact-intensive mass tort case with exhaustive taking of documentary evidence and oral testimony by pharmaceutical and medical experts, no German judge would adjudicate just on the basis of English original documents. The risk of being reversed on appeal for lack of language expertise would be much too high. Given the fact that most of the evidence in the current case is in English, there would be significant translation costs to be borne by both sides.

18. The Zekoll Declaration states that "... the time for fully litigating a civil matter before a court of first instance amounted on average 7-to-8 months. Proceedings in the appellate courts typically take between 7-to-9 months in civil cases." (*Id.* at ¶ 7). These figures,

however, refer to average cases. As pointed out before, the current one is a complex and fact-intensive mass tort case with exhaustive taking of documentary evidence and oral testimony by pharmaceutical and medical experts. Accordingly, the proceeding of first instance before the state district court (trial court) would take considerably longer, probably several years. Likewise, the proceeding of second instance (court of appeals), which under German law is twofold (appeal to the Court of Appeals and subsequent appeal to the Federal Supreme Court), would again take several years. Given the twofold appeal proceeding, it is possible, or even probable, that an U.S. proceeding would be speedier than a proceeding before a German Court.

I declare under the penalty of perjury and under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing is true and correct.

Done and executed in Freiburg, Germany on November 15, 2007.



Professor Dr. Hanno Merkt, LL.M. (Univ. of Chicago)

**EXHIBIT A**

To

DECLARATION OF PROFESSOR HANNO MERKT

# HANNO MERKT

## EDUCATION

First State Examination, University of Bonn, January 1987

Dr. iur. , University of Münster, April 1989

LL.M. (Master of Laws) University of Chicago, July 1989

Dr. habil., University of Hamburg, January 2000

## PROFESSIONAL AND TEACHING EXPERIENCE

Research Associate, Max-Planck-Institute for International and Comparative Law in Hamburg, 1990 - 2000

Lecturer in Law, Universit of Hamburg, 1997 - 2000

Visiting Scholar, New York University, Summer 1998

Professor of Law, University of Regensburg Faculty of Law, 2000

Professor of Law (full tenure), Alfried-Krupp-Chair for Private Law and Business Law, Bucerius Law School Hamburg, 2000 – 2003

Visiting Scholar, University of Chicago, Summer 2002

Professor of Law (full tenure), Director of the Institute of International and Comparative Law, Albert-Ludwigs-Universität Freiburg, since 2003

Visiting Profesor of Law, University of Ulm, Summer 2004

Visiting Professor, University of Vaduz / Liechtenstein, Summer 2005

Visiting Scholar, Harvard Law School, Summer 2006

## MEMBERSHIPS (ELECTED)

Schmalenbach-Association for Business Economics, since 2001

German Association for International Law, since 2003

Association for InternationalCivil Procedure Law, since 2003

Association for Social Politics (Verein für Socialpolitik), since 2005

Research Associate, European Corporate Governance Institute (ECGI), since 2007

**BAR ADMISSIONS**

New York Bar since 1990

Hamburg Bar 1993-2003

**COURT APPOINTMENT**

Court of Appeals of Karlsruhe, Germany since 2007

**EXHIBIT B**

To

DECLARATION OF PROFESSOR HANNO MERKT

Erwin Deutsch · Hans-Dieter Lippert
(Hrsg.)

# Kommentar zum Arzneimittelgesetz (AMG)

Zweite Auflage

Unter Mitarbeit von
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# Vorwort

Die deutsche Gesetzgebung zum Arzneimittelrecht entbehrt nicht einer gewissen Tragik. Kaum hatte der Gesetzgeber mit den Arzneimittelgesetzen 1961 den bis dahin entstandenen zersplitterten und unbefriedigenden Rechtszustand beseitigt, scheiterte dieses Gesetz kläglich an seiner ersten Bewährungsprobe, dem Contergan-Komplex.

Auch dem seit 1976 geltenden Folgegesetz blieben die Bewährungsproben nicht erspart. Obwohl es sich im großen und ganzen als taugliches Instrument eines vernünftigen Verbraucherschutzes auch in Zeiten europäischer Gesetzgebung erwiesen hat, ist ihm anzumerken, dass es durch die Berücksichtigung der Vorschriften des europäischen Gesetzgebers an Übersicht verloren hat. Auch durch die Problematik von HIV-verseuchten Blutprodukten traten die Grenzen des Gesetzes deutlich zutage. Letztlich gelang es dem Gesetzgeber auch hier nur mittels eines Sondergesetzes, dem HIV-Hilfegesetz, für einen berechtigten Interessenausgleich zu sorgen.

Seit seinem Inkrafttreten hat das Arzneimittelgesetz 1976 vierzehn Gesetzesnovellen erlebt, im Schnitt rund alle 3 Jahre eine. Demjenigen, der sich mit dem Arzneimittelrecht zu befassen hat und sich in dieses Rechtsgebiet einarbeiten möchte, stehen zwei große Loseblatt-Kommentare und neuestens ein Kurzkommentar zur Verfügung sowie die Einführung, die Deutsch, die in seinem Lehrbuch "Medizinrecht" gibt. Das vorliegende Werk befindet sich auf dem (zugegeben fragilen) Stand der 14. Novelle zum AMG.

Der vorliegende Kommentar möchte als Gegenstück zu den beiden großen Kommentaren und als Ergänzung zum Kurzkommentar eine komprimierte Einführung in das Gesetz geben und so die Lücke zwischen dem Lehrbuch und diesen Kommentaren schließen. Auf künftige Änderungen, die es sicher geben wird, kann so mit einer Neuauflage, die die aktuelle Kommentierung bietet, schnell reagiert werden.

Neu zum Autorenteam gestoßen ist Frau Professorin Brigitte Tag, Universität Zürich. Als ausgewiesene Spezialistin auf dem Gebiet des Nebenstrafrechts, wird sie sukzessive die zahlreichen Strafvorschriften und Ordnungswidrigkeiten überarbeiten und wo nötig neu kommentieren. Der Beginn wird mit dieser zweiten Auflage gemacht.

## SECHZEHNTER ABSCHNITT
## HAFTUNG FÜR ARZNEIMITTELSCHÄDEN

### Vorbemerkungen vor §§ 84ff.

Die Haftung für Arzneimittelschäden hat eine besonders ausführliche und liebevolle Regelung erfahren. Dennoch sind selten Haftungsfälle vor die Gerichte gekommen. Insgesamt ist es erstaunlich, dass die Verschuldenshaftung der Ärzte viel häufiger eingreift als die Gefährdungshaftung der Arzneimittelhersteller. Der Gesetzgeber hat für übermäßige Neben- und Wechselwirkungen eine Gefährdungshaftung eingeführt, für nicht zureichende Hinweise einer Verschuldenshaftung. Beide führen zum Schadensersatz und zum Schmerzensgeld. Die Haftung hat durch eine Zwangshaftpflichtversicherung abgesichert worden zu sein. Die Deckungsvorsorge beträgt für jedes zugelassene Arzneimittel € 120 Millionen. Sie wird von einem Pharmapool aufgebracht, wobei allerdings die für den Hersteller zunächst zuständige Haftpflichtversicherung für einen Grundbetrag gerade zu stehen hat. Insgesamt zeigt der sechzehnte Abschnitt, dass sowohl eine Verschuldens- als auch eine Gefährdungshaftung die notwendige Arzneimittelhaftung immer noch nicht sicher erfasst.



### § 84
### Gefährdungshaftung

**(1) Wird infolge der Anwendung eines zum Gebrauch bei Menschen bestimmten Arzneimittels, das im Geltungsbereich dieses Gesetzes an den Verbraucher abgegeben wurde und der Pflicht zur Zulassung unterliegt oder durch Rechtsverordnung von der Zulassung befreit worden ist, ein Mensch getötet oder der Körper oder die Gesundheit eines Menschen nicht unerheblich verletzt, so ist der pharmazeutische Unternehmer, der das Arzneimittel im Geltungsbereich dieses Gesetzes in den Verkehr gebracht hat, verpflichtet, dem Verletzten den daraus entstandenen Schaden zu ersetzen. Die Ersatzpflicht besteht nur, wenn**

1. **das Arzneimittel bei bestimmungsgemäßem Gebrauch schädliche Wirkungen hat, die über ein nach den Erkenntnissen der medizinischen Wissenschaft vertretbares Maß hinausgehen oder**
2. **der Schaden infolge einer nicht den Erkenntnissen der medizinischen Wissenschaft entsprechenden Kennzeichnung, Fachinformation oder Gebrauchsinformation eingetreten ist.**

**(2) Ist das angewendete Arzneimittel nach den Gegebenheiten des Einzelfalls geeignet, den Schaden zu verursachen, so wird vermutet, dass der Schaden durch dieses Arzneimittel verursacht ist. Die Eignung im Einzelfall beurteilt sich nach der Zusammensetzung und der Dosierung des angewendeten Arzneimittels, nach der Art und Dauer seiner bestimmungsgemäßen Anwendung, nach dem zeitlichen Zusammenhang mit dem Schadenseintritt, nach dem Schadensbild und dem gesundheitlichen Zustand des Geschädigten im Zeitpunkt der Anwendung sowie allen sonstigen Gegebenheiten, die im Einzelfall für oder gegen die Schadensverursachung sprechen. Die Vermutung gilt nicht, wenn ein anderer Umstand nach den Gegebenheiten des Einzelfalls geeignet ist, den Schaden zu verursachen. Ein anderer Umstand liegt nicht in der Anwendung weiterer Arzneimittel, die nach den Gegebenheiten des Einzelfalls geeignet sind, den Schaden zu verursachen, es sei denn, dass wegen der Anwendung dieser Arzneimittel Ansprüche nach dieser Vorschrift aus anderen Gründen als der fehlenden Ursächlichkeit für den Schaden nicht gegeben sind.**

**(3) Die Ersatzpflicht des pharmazeutischen Unternehmers nach Absatz 1 Satz 2 Nr. 1 ist ausgeschlossen, wenn nach den Umständen davon auszugehen ist, dass die schädlichen Wirkungen des Arzneimittels ihre Ursache nicht im Bereich der Entwicklung und Herstellung haben.**